

## REMARKS / ARGUMENTS

### **Status of Claims**

Claims 2-55, 57, 59 and 60 are pending in the application. Claims 2-55, 57, 59 and 60 stand rejected.

Applicants have amended Claims 57, 59, and 60, leaving Claims 2-55, 57, 59 and 60 for consideration upon entry of the present amendment.

Applicants respectfully request the Examiner reconsider and withdraw the pending rejections under 35 U.S.C. § 103 in light of the attached amendments and the remarks provided below.

### **Examiner's Response to Arguments, Section (iii)**

As set forth in the Office Action at page 2, the Examiner has requested that Applicants provide the Examiner with support for the present and previously filed amendments within the priority document submitted on November 9, 2001. Applicants assume the Examiner is referring to the amendments filed on August 20, 2007 due to lack of any other description by the Examiner, and Applicants submit that all claim amendments presently attached, and previously filed, have full support in the present specification and the priority document.

Applicants note, that the excerpts provided and quoted below, are to the best of Applicants' knowledge, representative of an English translation of the foreign priority document submitted on November 9, 2007. No certified English translation has been obtained. However, Applicants believe that all claim amendments are fully supported by both the present specification and the foreign priority document.

For example, as set forth in paragraph [0024-0027] of the subject application and page 4, lines 26-35 through page 5, lines 1-17, "[f]igures 1 and 2 illustrate, in general, the stages of operation on a stenosis by means of an endovascular prosthesis," "the endovascular prosthesis 2 is a deployable cylinder," and "the method according to the invention provides for simulation of the stages described above" (emphasis added, French

language translation). Furthermore, as set forth in paragraph [0037] of the subject application and page 8, lines 2-6, “it is also possible in the course of an operation ... to execute the method and to visualize the simulated final state of the operation” (emphasis added, French language translation). More clearly, the subject specification and priority document set forth the actual operation on a stenosis and the simulation of the actual operation, including simulation of the endovascular prosthesis which is a deployable or real prosthesis.

Therefore, Applicants submit that all amendments submitted previously and presently have full support in the specification as originally filed and the certified priority document submitted on November 9, 2001, as shown in the examples given above in addition to other portions of the specification and priority document.

#### **Entry of Amendments After the Final Rejection**

Applicants respectfully request entry of the present amendments after the issuance of the final rejection for the following reasons. The amendments to claims 57, 59, and 60 do not raise any new issues as the amendments are clarifying in nature.

For example, as set forth in the amendment filed August 20, 2007, claims 57, 59, and 60 set forth in their respective preambles “simulate in the course of an actual interventional operation” or “simulating in the course of an actual interventional operation”. As is apparent to one of ordinary skill in the art, the claims as previously presented are directed to simulation during the course of an actual interventional operation. Therefore, the amendments to claims 57, 59, and 60 add clarity by merely emphasizing “thereby enabling simulation in the course of the actual interventional operation, to take the present stage of actual operational parameters into account so that a simulated final state of the actual interventional operation ~~can be~~ is visualized” (amendments indicated with strikethroughs and underlined text).

Furthermore, it is respectfully submitted that the amendments only further state limitations already present in the preambles of the claims. Therefore the amendments include limitations which have been previously considered by the Examiner.

As such, Applicants respectfully request entry of the present amendments as the amendments do not raise any new issues.

**Claim Rejections Under 35 U.S.C. § 103(a) (Haridas and Gorman)**

Claims 2-55, 57, and 59-60 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Haridas et al., Medical Device and Diagnostic Magazine “Predictive Analysis at the Forefront of Medical Product Development”, hereafter referred to as Haridas, in view of Gorman et al. “Simulation and Virtual Reality in Surgical Education”, hereafter Gorman. Applicants respectfully traverse this rejection for the following reasons:

***Haridas does not disclose or suggest features of the claims***

As set forth in the Office Action at page 3, the Examiner asserts that Haridas discloses “enabling in the course of the actual interventional operation, to take the present stage of operational parameters into account so that a simulated final state of the actual interventional operation can be realized.”

Applicant respectfully disagrees for the following reasons. Haridas discloses “...Such material data allow the simulation of the device tissue interaction problem to be exercised over the entire range of statistical variability, allowing the function of the device and the materials to be fully assessed.” [Haridas, Page 4, “What if” Material Sensitivity Studies]. Haridas also discloses “...Additional tests to characterize the response of the polymer under constrained conditions, such as biaxial stretching, must be performed to generate the appropriate material constants for input into the finite element calculations.” [Haridas, Page 5, paragraph 1]. Haridas further discloses, “...finite element modeling of the balloon positioned within the lumen of the stenosis and then inflated against a virtual blocked vessel (Figures 8-10).” [Haridas, Page 6, paragraph 1].

Thus, Haridas discloses a modeling method that involves a methodology absent disclosure or suggestion of real time steps or any actual interventional operation. Therefore, Haridas cannot disclose or suggest any actual interventional operation or simulation of a final state of the interventional operation.

As such, Haridas does not disclose or suggest “enabling simulation in the course of the actual interventional operation, to take the present stage of actual operational parameters into account so that a simulated final state of the actual interventional operation is visualized” as set forth in independent claims 57, 59, and 60.

Accordingly, Applicant submits that Haridas does not disclose all of the claimed elements arranged as in the claim. However, the Examiner appears to contend that Gorman discloses simulation in the course of an actual interventional operation. Applicants respectfully disagree.

***Gorman does not make up for the deficiencies of Haridas***

Gorman is directed to simulation and virtual reality in surgical education (see Gorman, title and introductory paragraph). Gorman further discloses virtual reality techniques for performing operations (see ‘Virtual Reality,’ page 1204; and ‘Applications,’ page 1205). However, Gorman makes it clear that simulation and virtual reality are separate aspects of the disclosure, stating that virtual reality may be used in real applications absent any disclosure of simulation used in real surgeries (see Gorman, ‘Applications,’ page 1205).

However, it appears that the Examiner contends that Gorman’s disclosure of Virtual Reality techniques for surgery are actually simulations of an actual surgery. Applicants respectfully disagree.

For example, the Examiner states at page 5 of the Office Action that Real-Time simulation discloses an actual interventional operation and simulation based on the actual interventional operation. Applicants submit that Real-Time simulation is, as commonly known to one of ordinary skill in the art, simulation of an environment with updates occurring in a time frame relating to real-time. For example, as stated by Gorman, “real-time simulation ... involve[s] the computer modeling of events so that they proceed within a defined range of their natural occurrence” (see Gorman, page 1204, under ‘Simulation’). More clearly, these are merely simulations and do not disclose or suggest simulations occurring during an actual event.

Furthermore, the Examiner states at page 5 of the Office Action that Image Guidance discloses an actual interventional operation and simulation based on the actual interventional operation. Applicants submit that Image Guidance is, as commonly known to one of ordinary skill in the art and as used by Gorman, image-guided surgery or computer-aided surgery. Gorman discloses that “[n]avigation in surgery relies on stereotactic principles, based on the ability to locate a given point using geometric references. Applicants submit that computer-aided navigation in surgery is not simulation during surgery, nor is it suggestion of any simulation during the course of an actual surgery.

Thus, Gorman does not disclose or suggest “enabling simulation in the course of the actual interventional operation, to take the present stage of actual operational parameters into account so that a simulated final state of the actual interventional operation is visualized” as set forth in independent claims 57, 59, and 60.

Therefore, as argued above, Gorman does not disclose an actual interventional operation and simulation based on the actual interventional operation as stated by the Examiner, and therefore does not make up for the deficiencies noted above regarding Haridas.

In view of the amendments and foregoing remarks, Applicant submits that Haridas and Gorman, alone or in any combination, do not disclose or reasonably suggest each and every element of the claimed invention arranged as claimed and therefore cannot render the present claims unpatentable.

Accordingly, Applicant respectfully submits that the Examiner’s rejection under 35 U.S.C. §103(a) has been traversed, and requests that the Examiner reconsider and withdraw of this rejection.

**Claim Rejections Under 35 U.S.C. § 103(a) (Haridas and Gross)**

Claims 2-55, 57, and 59-60 stand rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Haridas et al., Medical Device and Diagnostic Magazine

“Predictive Analysis at the Forefront of Medical Product Development”, hereinafter referred to as Haridas in view of Gross “Computer Graphics in Medicine: From Visualization to Surgery Simulation”, hereinafter Gross. Applicants respectfully traverse this rejection for the following reasons:

***Haridas does not disclose or suggest features of the claims***

As set forth in the Office Action at page 3, the Examiner asserts that Haridas discloses “enabling in the course of the actual interventional operation, to take the present stage of operational parameters into account so that a simulated final state of the actual interventional operation can be realized.”

Applicant respectfully disagrees for the following reasons. Haridas discloses “...Such material data allow the simulation of the device tissue interaction problem to be exercised over the entire range of statistical variability, allowing the function of the device and the materials to be fully assessed.” [Haridas, Page 4, “What if” Material Sensitivity Studies]. Haridas also discloses “...Additional tests to characterize the response of the polymer under constrained conditions, such as biaxial stretching, must be performed to generate the appropriate material constants for input into the finite element calculations.” [Haridas, Page 5, paragraph 1]. Haridas further discloses, “...finite element modeling of the balloon positioned within the lumen of the stenosis and then inflated against a virtual blocked vessel (Figures 8-10).” [Haridas, Page 6, paragraph 1].

Thus, Haridas discloses a modeling method that involves a methodology absent disclosure or suggestion of real time steps or any actual interventional operation. Therefore, Haridas cannot disclose or suggest any actual interventional operation or simulation of a final state of the interventional operation.

As such, Haridas does not disclose or suggest “enabling simulation in the course of the actual interventional operation, to take the present stage of actual operational parameters into account so that a simulated final state of the actual interventional operation is visualized” as set forth in independent claims 57, 59, and 60.

Accordingly, Applicant submits that Haridas does not disclose all of the claimed elements arranged as in the claim. However, the Examiner appears to contend that Gross

discloses simulation in the course of an actual interventional operation. Applicants respectfully disagree.

***Gross does not make up for the deficiencies of Haridas***

Gross is directed to simulation and visualization of surgery using computer graphics (see Gross, title and abstract). Gross discloses surgery simulation as “virtual operations,” where virtual tools are used to simulate a surgery (see Gross, pages 54-55, ‘The Future: Virtual Operation and Surgery Simulation’). Applicants submit that this is disclosure of mere simulation of a proposed surgery, and lacks any disclosure of simulation during the course of an actual operation.

However, it appears that the Examiner contends that Gross’ disclosure of Virtual Reality techniques for surgery are actually simulations during an actual surgery. Applicants respectfully disagree.

For example, the Examiner states at page 5 of the Office Action Data Acquisition and Analysis for surgery simulation is disclosure of an actual interventional operation and simulation based on the actual interventional operation. Applicants submit that data acquisition and analysis, as presented by Gross, is merely disclosure of using 3-dimensional surface data acquisition for use in surgery simulation (see Gross, page 55, ‘Data Acquisition and Analysis’). More clearly, Gross is fully absent of any disclosure or suggestion of acquisition of data occurring during an actual intervention operation.

Thus, Gross does not disclose or suggest “enabling simulation in the course of the actual interventional operation, to take the present stage of actual operational parameters into account so that a simulated final state of the actual interventional operation is visualized” as set forth in independent claims 57, 59, and 60.

Therefore, as argued above, Gross does not disclose an actual interventional operation and simulation based on the actual interventional operation as stated by the Examiner, and therefore does not make up for the deficiencies noted above regarding Haridas.

In view of the amendments and foregoing remarks, Applicant submits that Haridas and Gross, alone or in any combination, do not disclose or reasonably suggest

each and every element of the claimed invention arranged as claimed and therefore cannot render the present claims unpatentable.

Accordingly, Applicants respectfully submit that the Examiner's rejection under 35 U.S.C. §103(a) has been traversed, and requests that the Examiner reconsider and withdraw of this rejection.



### **CONCLUSION**

In light of the forgoing, Applicant respectfully submits that the Examiner's rejections under 35 U.S.C. §103(a), have been traversed, and respectfully requests that the Examiner reconsider and withdraw these rejections.

If a communication with Applicant's Attorneys would assist in advancing this case to allowance, the Examiner is respectfully requested to contact the undersigned so that any such issues may be promptly resolved.

The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 06-1130.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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